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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,445	06/11/2001	Gregory R. Mundy	OSTS:003USD2	4570

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

9

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/879,445

Applicant(s)

MUNDY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The response to the restriction requirement, filed December 9, 2002, is acknowledged.

The restriction requirement is withdrawn in light of the preliminary amendment that was previously filed, canceling claims 1-24. The examiner regrets the inconvenience caused by the failure to note the preliminary amendment.

2. The preliminary amendment, filed June 11, 2001, has been entered. Claims 1-24 were canceled.

Claims 25-29 are pending and examined on the merits.

### *Information Disclosure Statement*

3. The references cited in the IDS were not considered because the parent file is unavailable. Applicant is invited to supply curtesy copies of the cited references.

### *Drawings*

4. The drawings are objected to, because Figure 4 is described in the specification as showing the structure of dexamethasone. A search by STIC demonstrated that the structure shown in Figure 4 is not that of dexamethasone. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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***Claim Objections***

5. Claim 25 is objected to because of the following informalities: the term PTH-rP should be written out in full with the abbreviation in parenthesis at the first instance in the claims.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite, because the active steps of the claimed method do not correlate with the purpose of the method as recited in the preamble. The preamble is directed to a method of regulating PTH-rP production, whereas step (i) is directed to identifying a compound that alters PTH-rP activity.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirola (Pirola et al, Journal of Biological Chemistry, 268(3): 1987-1994, 1993).

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Claims 25 and 28 are drawn to methods of regulating PTH-rP production, where altering PTH-rP "activity" is interpreted as increasing production of PTH-rP.

Pirola teaches a method for increasing the production of PTH-rP in vascular smooth muscle cells (SMC) by the addition of angiotensin II to SMC (see page 1988, 2<sup>nd</sup> col., Results; and 1989, 1<sup>st</sup> and 2<sup>nd</sup> col., bridging paragraph). Thus, Pirola teaches a method that is the same as that claimed.

8. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Torring (Torrington et al, Endocrinology, 131(1): 5-13, 1992).

Claim 25 is interpreted to read on methods of regulating PTH-rP activity, because the first active step is directed to identifying a compound that alters PTH-rP activity.

Torrington teaches a method for inhibiting the activity of PTH-rP to cause hypercalcemia in rats (see page 8, 2<sup>nd</sup> col., 2<sup>nd</sup> para.) by the co-administration of interleukin-1 $\alpha$  (IL-1 $\alpha$ ). Thus, Torring teaches a method that is the same as that claimed.

9. Claims 25, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Deftos (Deftos et al, Endocrinology, 125: 563-565, 1989, ABSTRACT only).

Deftos teaches a method of inhibiting secretion of PTHrP by the addition of Chromogranin A –derived peptides to cultures of BEN human lung tumor cells. Deftos also teaches a method of increasing secretion of PTHrP by the addition of calcitonin to cultures of BEN human lung tumor cells. Thus, Deftos teaches methods that are the same as that claimed.

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10. Claims 25, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Allinson (Allinson and Drucker, Cancer Res. 52: 3103-3109, 1992).

Allinson teaches a method of inhibiting the expression of PTH-rP by the addition of dexamethasone to cultures of keratinocytes. Allinson also teaches a method of increasing the expression of PTH-rP by the addition of cyclohexamide to cultures of keratinocytes. Thus, Allinson teaches methods that are the same as that claimed.

11. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi (U.S. Patent 5,246,700; issued September 21, 1993).

Yamaguchi discloses a method of administering interleukin-4 to nude mice to test for reduction of PTH-rP-induced hypercalcemia. Yamaguchi claims methods of treatment comprising the administration of interleukin-4 to patients suffering from a bone disorder caused by dysregulation of calcium. Thus, Yamaguchi discloses methods that are the same as that claimed.

12. Claims 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Rabbani (Rabbani et al, Endocrinology, 136(12): 5416-5422, 1995, Dec.).

Rabbani teaches a method of regulating PTH-rP production in Leydig tumor cells (H-500 cells) by the transfection of PTH-rP antisense RNA. Rabbani demonstrates that contacting the cells with the antisense results in decreased secretion of PTH-rP by H-500 cells and that the activity of PTH-rP to increase plasma calcium is also inhibited (see abstract). Thus, Rabbani teaches a method that is the same as that claimed.

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*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
February 22, 2003

  
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